Moving Toward a Unified Reimbursement Process across Europe through the Creation of Specific Pathways for New & Existing Medical Technologies, while Meeting Increasing Clinical Data Requirements and Maximizing Positive HTA Decisions

PROGRAM OVERVIEW:
Throughout Europe, medical device corporations are working towards integrating new technologies as quickly and as effectively as possible. As the market has continued to expand, executives are continually looking to find new strategies for addressing the myriad delays and set-backs that they face in bringing these products onto the market. While a unified system is far from coming into reality, manufacturers are striving to set a single pathway for gaining reimbursement for their new and existing product offerings.

A key strategy that will be discussed during this program is setting that single pathway for successfully integrating new products into the market. Rather than delving into specific case studies examining each individual country or market, case studies will examine specific products that have seen wild successes in their integration processes. Through the careful discussion and debate surrounding these product success stories, executives will have a far more thorough understanding of what needs to be accomplished within their own organizations in order to match these successes.

With health technology assessments continuing to play an important role within decision making for many national health systems, representatives from NICE, IQWiG and HAS will again be on hand to discuss recent cases and trends. With EUenetHTA also increasingly relevant and making strides to a more unified HTA process across Europe, attendees will again gain superior knowledge to help support their product integrations.

As with all Q1 programs, a considerable mix of presenters including top-industry executives alongside regulatory bodies and other experts will allow this program to meet the educational requirements of participants. With seamlessly melded formal and informal networking opportunities, the focus will not singularly lie on educational aspects, but also networking, informal knowledge share and relationship building across the industry.

DISTINGUISHED PRESENTERS INCLUDE:

Rodamni Peppa
Director Health Economics & Government Affairs, International
BOSTON SCIENTIFIC

Pascale Brasseur
Director of Health Economics and Reimbursement
MEDTRONIC

Muriel Granger
Health Economics & Governmental Affairs, Regulatory & Quality Affairs Director
BOSTON SCIENTIFIC FRANCE

Amélie Ballière-Joachim
Marketing Manager EMEA Knee Marketing
ZIMMER

Gijs Hubben
CEO
BASECASE

Mirella Marlow
Programme Director, Devices & Diagnostic Systems, Center for Health Technology Evaluation
NICE

Rachele Busca
CardioVascular Reimbursement & Health Economics Manager Europe
MEDTRONIC

Markus Ott
VP EMEA Health Economics & Reimbursement
COVIDIEN

Tom Ladds
International Clinical Instructor
PROSTALUND

Gerald Schnell
Partner
SIMON-KUCHER & PARTNER

Isabel Henkel
Director Access & Reimbursement
JOHNSON & JOHNSON MEDICAL

Matthias Khylstedt
CEO
SYNERGUS
Reimbursement systems across Europe differ from one another and this terrible lack of harmonization poses great challenge to device companies seeking reimbursement for their products. From undeniable cost-savings to conditioning of time frames, the benefits in moving forward with a centralized approach are numerous. Opening the debate on the feasibility of a unified approach to several markets at once will allow reimbursement executives to understand how to access more markets in less time.

- Similarities between reimbursement processes across Europe
- Raising concerns on various evidence requirements
- Repositioning of data from one country to another

Markus Ott, VP EMEA Health Economics & Reimbursement

10:15 UNDERSTANDING THE UNDERLYING DRIVERS OF THE EUROPEAN REIMBURSEMENT SYSTEMS

When looking at reimbursement, it is essential to understand what can drive a change in a reimbursement system. We will illustrate key-issues that are important to understand in order to make the new therapy “reimbursable”.

Matthias Khylstedt, CEO

SYNERGUS

11:00 COFFEE & NETWORKING BREAK

11:15 PANEL DISCUSSION: SUCCESSFULLY EXHIBITING EVIDENCE TO OBTAIN REIMBURSEMENT OF AN INNOVATIVE DEVICE

In this era of rapid technology progress, innovation is the driving force of the medical device industry. Developing a value dossier for new technologies is extremely challenging as it must fully illuminate clinical and economic data that may not as yet be entirely developed or understood, especially taking into account longer-term utilization figures. Having a frank dialogue within the industry related to what evidence has worked in specific situations will enable executives to have a fuller understanding of evidence requirements, and how to best present these in such situations.

- Understanding the reimbursement framework in the targeted market
- Emphasizing economic added-value
- Considering evidence generation costs

Anthony Dixon
Marketing Director EMEA

SIRTAX MEDICAL

Mattias Khylstedt
CEO

SYNERGUS

Gijs Hubben
CEO

BASECASE

12:00 COMMUNICATING ECONOMIC VALUE TO HEALTHCARE PROVIDERS – DELIVERING TAILORED VALUE MESSAGES IN A VISUAL, INTERACTIVE FORMAT USING THE BASECASE PLATFORM

In a changing healthcare landscape, the success of market adoption of devices is increasingly dependent on presenting a compelling business case to healthcare providers, using complex spreadsheets. BaseCase provides cloud-based software to create visual and interactive sales applications that run on any device, including the iPad. In this case-study, the co-presenters will outline how Zimmer leveraged BaseCase technology to successfully communicate the economic value proposition for a key orthopedic product.

- How to visualize complex economic data
- How to deliver a tailored value story to each customer
- How to distribute sales tools to a global sales force

Gijs Hubben
CEO

BASECASE

Amélie Bailliere-Joachim
Marketing Mgr. EMEA Knee Marketing

ZIMMER

12:30 LUNCHEON FOR ALL SPEAKERS, SPONSORS & ATTENDEES

1:30 OVERCOMING LIMITATIONS IN RANDOMIZED CONTROLLED TRIALS TO SUPPORT ACCESS

Throughout Europe, and indeed throughout much of the world, healthcare payers are increasingly requesting data obtained from Randomized Controlled Trials. While these types of trials certainly have considerable merit, for many or even most medical devices, they are not only not appropriate, but also not viable. Reimbursement executives need to understand what other types of trials can achieve similar success compared to RCTs, and how to work with various constituents in order to achieve reimbursement success with the data generated.

- Pros and cons of RCTs in medical device studies
- Examining device-specific alternative trials
- Submitting data to health authorities by other means

Dominik Straumann, Health Economics Project Manager

B. BRAUN MEDICAL

2:15 BEST PRACTICES IN PLANNING FOR REIMBURSEMENT IN EUROPE

With reimbursement of medical devices continually increasing in complexity, it is essential for manufacturers to consider reimbursement from the outset of product design and testing. As many organizations wait to initiate their reimbursement plans once CE mark is obtained, those planning for reimbursement from the outset often find greater success in bringing their technologies to market. Through a thorough examination of early-stage reimbursement strategies and planning, participants in this session will understand how to initiate a reimbursement strategy from the outset of product development.

- The influence of reimbursement systems on the design of a device
- Early development of reimbursement strategies
- Benefits in conducting clinical trials in targeted markets
- Continuous improvement of the strategy throughout product development
- Examining competitive products in targeted markets

Rodamni Peppa, Director, Health Economics & Govt Affairs, International Medical Systems

3:00 EXAMINING TRENDS WITHIN MAJOR EUROPEAN MARKET HTAS

To successfully secure reimbursement of a device in key-European countries, it is extremely important for reimbursement teams to understand how the targeted market is evolving, and how these changes impact the HTAs. With the implementation of new legislations and increasing expectations from health authorities, HTAs are utilizing recent methods to examine medical devices and evaluate their purpose and value. Examine these trends through perspectives of HTA representatives from two large European markets who will provide reimbursement teams with clarifications on how to improve their reimbursement strategies.

GERMANY – IQWIG:

- Key differences for in vs. out-of hospital procedures
- Effectiveness as a base for HTA decisions
- New legislation ‘Versorgungsstrukturgesetz’ impact

Julia Kreis, Research Associate

IQWIG

UNITED KINGDOM – NICE:

- NHS reform impact
- Overview of the new NICE evaluation pathway
- Understanding NICE’s Medical Technology Evaluation Programme

Mirella Marlow, Programme Director, Devices & Diagnostic Systems, Center for Health Technology Evaluation

NICE

4:00 COFFEE & NETWORKING BREAK

4:15 DRG-BASED HOSPITAL PAYMENT AND MEDICAL INNOVATION IN EUROPE: RESULTS OF THE EURODRG PROJECT

The hospital payment system is one important factor influencing the adoption and use of technological innovation in health care. There have been concerns that Diagnosis Related Group (DRG)-based hospital payment systems, which are the principal means of hospital payment in the majority of OECD countries, may not provide the right set of incentives to encourage the desired adoption and use of technological innovation. Findings of the EuroDRG project concerning how DRG-based hospital payment systems deal with technological innovation have revealed that:

- Short-term payment mechanisms and long-term updating mechanisms differ greatly across the 12 European countries included in this study.
- Generous short-term payment instruments exist in some countries to provide additional payments to hospitals for making use of technological innovation (e.g., in Germany and France).
- Other countries update their DRG-based hospital payment systems very frequently and use more recent data for updates.

Wilm Quentin, Researcher, Dept of Health Services Management Technisches Universität Berlin

Member

EURODRG PROJECT

5:00 NHS REFORM: IMPACT ON MEDICAL DEVICE REIMBURSEMENT

The hospital payment system is one important factor influencing the adoption and use of technological innovation in health care. There have been concerns that Diagnosis Related Group (DRG)-based hospital payment systems, which are the principal means of hospital payment in the majority of OECD countries, may not provide the right set of incentives to encourage the desired adoption and use of technological innovation. Findings of the EuroDRG project concerning how DRG-based hospital payment systems deal with technological innovation have revealed that:

- Short-term payment mechanisms and long-term updating mechanisms differ greatly across the 12 European countries included in this study.
- Generous short-term payment instruments exist in some countries to provide additional payments to hospitals for making use of technological innovation (e.g., in Germany and France).
- Other countries update their DRG-based hospital payment systems very frequently and use more recent data for updates.

Julian Dunnnett, Reimbursement Specialist UK

AMERICAN MEDICAL SYSTEMS
DAY TWO / TUESDAY, JAN 24 / MEDICAL DEVICE REIMBURSEMENT CONFERENCE

8:00 REGISTRATION & COFFEE

8:20 CHAIRPERSON OPENING REMARKS
Gerald Schnell, Partner, SIMON-KUCHER & PARTNER

8:30 FORECASTING BENEFITS IN THE EUUNETHA JOINT ACTION
The European network for Health Technology Assessment commenced as a project conducted from 2006 to 2008, aiming at ultimately creating a sustainable network for HTAs across the continent. This project being successfully accomplished, EUUnetHTA has developed in 2010 the Joint Action, the objective being to stimulate collaboration between member HTAs. Through exchanging strategies and opinions, the network aspires at developing added value in communication between European HTAs and facilitating their approach from the life science industry, notably in the field of evidence requirements on new technologies. Addressing EUUnetHTA’s work towards European harmonization will allow a better understanding of the potential trends that will impact reimbursement activities in the years to come.

• Overview of the forthcoming Joint Action II & Cross-Border Directive
• Perspective from the medical device industry on EUUnetHTA projects
• Potential changes to come in pan-European reimbursement processes

Pascale Brasseur, Director of Health Economics and Reimbursement
MEDTRONIC
Medical Device Industry Representative
EUNETHTA STAKEHOLDERS FORUM

9:15 REIMBURSEMENT OF MEDICAL DEVICES IN EUROPE: HOW CLINICAL & ECONOMIC DATA SUPPORT ACCESS TO ADDITIONAL FUNDS
With such different market access and coverage policies across Europe, exhibiting the value of a device to HTAs and health authorities is a critical step in securing reimbursement for innovative medical devices, in particular if they are considered expensive. Some European countries have processes in place to secure reimbursement of innovation, and clinical and economic requirements differ by country. Through gathering and balancing the appropriate data and numbers, reimbursement executives will be able to present a cohesive and thorough view of their innovative device to ultimately access targeted markets.

• Reimbursement pathway for medical devices in Europe
• Processes to integrate innovative and more costly devices in the reimbursement country schemes
• Understanding the increasing demand for evidence from decision makers

Rachele Busca, CardioVascular Reimbursement & Health Economics Manager Europe
MEDTRONIC

10:00 COFFEE & NETWORKING BREAK

10:30 DESIGNING AN EFFECTIVE REIMBURSEMENT STRATEGY: WHAT WE CAN LEARN FROM SUCCESS AND FAILURE CASES
• Success factors and pitfalls
• Implications for designing an effective reimbursement strategy
• Organizational requirements

Gerald Schnell, Partner, SIMON-KUCHER & PARTNER

11:15 BEST PRACTICES: OVERCOMING CHALLENGES IN THE INTEGRATION OF INNOVATIVE DEVICES IN GERMANY & FRANCE
To answer the increasing demand for more specific medical products from patients and health administrations, device manufacturers are continuously developing modified and innovative products that very often require upgrading of existing reimbursement systems across Europe. In key-European countries as Germany and France that utilize DRG-type payment systems, the main challenge faced by reimbursement teams is to assess if the product can fit into an existing framework. With perspectives from different device manufacturing companies, reimbursement teams taking part in this session will have a better understanding of which strategies are most efficient to successfully integrate medical products in both key markets.

GERMANY:
• Understanding the current G-DRG mechanism
• Examining valuable base pricing trends
• Overview of the NUB Process
• Industry’s forecast of ‘Versorgungsstrukturgesetz’ impact

Isabel Henkel, Director Access & Reimbursement
JOHNSON & JOHNSON MEDICAL

FRANCE:
• Recognizing GHS and GHS systems
• Identifying appropriate CCAM and LPPR codes
• Utilizing the CNEDiMTS guide to the French market

Muriel Granger, Health Economics & Governmental Affairs, Regulatory & Quality Affairs Director
BOSTON SCIENTIFIC FRANCE

12:00 LUNCHEON FOR ALL SPEAKERS, SPONSORS & ATTENDEES

1:00 EFFECTIVE TRAINING OF SALES TEAMS ON REIMBURSEMENT PROCESSES
In order to maximize reimbursement and access across European markets, teams of executives including reimbursement departments, health economics, clinical & sales teams must work together closely to best exhibit the value proposition for each product. As sales teams are often the first line of communication with health authorities and physicians, they must be fully versed in not only the clinical benefits of the products, but also fully cognizant of the payment systems in place. With each system incorporating different value points, it is increasingly critical that reimbursement teams work together closely on training their sales representatives on how to best approach and succeed in these specific markets. Through the development of effective training programs and a close bond, organizations will find great success in commercializing their new and existing products.

• Implementing reimbursement training courses for sales forces
• Development of specific training for singular markets
• Recognizing legal compliance in product promotion

Tom Ladds, International Clinical Instructor
PROSTALUND

1:45 PHARMACEUTICAL VS MEDICAL DEVICES: SIMILARITIES AND DIFFERENCES IN SECURING REIMBURSEMENT
Requirements and expectations from health authorities and HTAs to prove the value of pharmaceuticals and devices are increasingly alike. Unfortunately, these requirements are incredibly limiting for the medical device industry, as the reimbursement of pharmaceutical therapies cannot possibly be considered in the same way as medical devices, which often require surgery, post-operation therapy, and in many cases, stay with the patient for life. Examining the similarities in pharmaceutical and device reimbursement roadmaps will allow constructive comparisons and forecasting of potential future trends in medical product reimbursements throughout Europe.

• Understanding current pharmaceutical reimbursement trends
• Addressing positive and negative parallels
• Forecast of potential alternatives to existing requirements

Anthony Dixon, Marketing Director EMEA
SI RTEX MEDICAL

2:30 LEGAL IMPLICATIONS & COMPLIANCE IN THE SALES & MARKETING OF MEDICAL DEVICES IN EUROPE
Over the course of the past several years, a number of high-profile cases have highlighted what has been considered inappropriate or non-compliant sales and marketing tactics within the medical device industry. Much of the information considered incorrectly utilized has related to various reimbursement structures which may or may not have been entirely accurate. While training sales and marketing teams on the appropriate use of reimbursement information is certainly a first step, organizations must also recognize the increasingly severe legal implications should a staff member inaccurately promote reimbursement to a potential doctor, hospital or health system.

• Recent cases in the medical device industry
• Specific country regulations
• Cross-border issues in FCPA

Christian Dekoninck, Counsel
CROWELL & MORING

3:15 CLOSING REMARKS & CONFERENCE CONCLUSION
WHO SHOULD ATTEND THIS Q1 CONFERENCE:
Executives that will find this program of greatest relevance are those currently working to secure funding, reimbursement and market access for innovative medical technologies throughout the European market. Job titles of those executives that will find this program to be most applicable to their job functions include Vice Presidents, Directors, and Heads of:
- Reimbursement
- Market Access
- Health Policy
- Government Affairs
- Health Outcomes
- Pricing
- Business Development
- Sales & Marketing

SPONSORSHIP OPPORTUNITIES:
At this time, there are a variety of sponsorship and exhibition opportunities available for companies wishing to increase their visibility and participation in the program, ranging from keynote speaking opportunities through to exhibit and documentation sponsors. Organizations most suitable for this type of exposure provide services and solutions including:
- Global Reimbursement & Market Access Consultants
- Regional Reimbursement Consultancies
- Market Access & Product Launch Services
- Data Management Providers
- Health Outcomes & Health Economics Experts
- Government Policy Consultants

CONTACT Q1 PRODUCTIONS:

CHICAGO
500 N. Dearborn, Suite 500
Chicago, IL 60654
Phone: 312.822.8100
Fax: 312.602.3834

LONDON
London House
271-273 King Street
London, W6 9LZ
Phone: +44 (0) 208 233 2833
Fax: +44 (0) 207 504 3792

MONTPELLIER, FRANCE
BAT Latecoere, 34134
Montpellier, France
Phone: +33 9889 99860
Fax: +1 312 602 3834

PREVIOUS ATTENDEES INCLUDE:
Director, Reimbursement, Acclarent (a J&J Company)
VP Int’l Government Affairs, Advanced Medical Optics
European Market Access Director, Alcon Laboratories
European Pricing Manager, Alcon Laboratories
Field Clinical Research Mgr. EMEA, AMS Europe
Reimbursement Specialist, Atos Medical
VP Gov’t Affairs & Health Policy, B.Braun
Associate Director, EMEA Health Outcomes, Baxter
European Director, Healthcare Initiatives, Biomet
Health Economics Manager, Biomet
Director, Global Reimbursement, Biotronik
Associate Director, Global Reimbursement, Biotronik
Mgr, Health Economics & Gov’t Affairs, Boston Scientific
FP&A Manager, Covidien
Director, Health Economics & Reimbursement, Covidien
General Manager, Europe, Cyberonics
Area Manager, UK & Ireland, Cyberonics
Sales Support Coordinator, Elekta Instruments
Associate Director, Global HEOR, Ethicon
European Business Director, Eurocor
Corporate Business Director, Eurocor
Sr. Director Value Propositions & Pricing, GE Healthcare
Deputy Head, Medical Device Assessment, HAS
Sr. Director, European Operations, Inspire Medical
Head, Non-Drug Interventions, IQWIG
Reimbursement Director, EMEA, Johnson & Johnson
Health Economics & Reimbursement, Johnson & Johnson
Sr. Manager, Health Economics & Reimbursement, KCI
Sr. Director, Health Economics & Reimbursement, KCI
Head, Healthcare Development, LifeScan
Director, Medical Affairs, Medical Device Works
Clinical Research Coordinator, Medical Device Works
Product Manager, Interventional, MedRad Europe
Manager, Reimbursement & HEOR, Medtronic
Reimbursement Director, Medtronic
Alliance Manager, Miltenyi Biotec
Quality Assurance & Regulatory Affairs Mgr, Miracor
Medical Director, Molnycke Healthcare
Program Director, Devices, NICE
Marketing Manager, Europe, Nuvasvie
Education Manager, Spinal, Orthofix
Product Marketing Manager, Ossur Europe
Director, Medical Affairs, Otto Bock
Manager, Health Economics, pfm medical
VP International Sales, ProstaLund
Head of Payer Marketing, Roche
Marketing Director, EMEA, Sirtex Medical
Business Development Manager, sorbion AG
Global Market Access & Reimbursement Mgr., Sorin
Health Economics Manager, Sorin
Marketing Manager, Spinelab
Director, Health Economics & Health Policy, Stryker
Health Economics & Reimbursement Manager, Stryker
Business Development, Summit Medical
European Reimbursement Manager, Syntes
VP Market Development & Education, Syntes
VP Sales & Marketing, Volcano Europe
Sr. Director, Clinical & Regulatory, Wright Medical
AND MANY MORE!